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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,296	06/02/2005	Manuela Guglielmo	5002-1074	8261
<div>465                      7590                      07/26/2010</div> <div>YOUNG &amp; THOMPSON 209 Madison Street Suite 500 Alexandria, VA 22314</div>				
EXAMINER				
GULLEDGE, BRIAN M				
ART UNIT		PAPER NUMBER		
1612				
NOTIFICATION DATE		DELIVERY MODE		
07/26/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

### Office Action Summary

**Application No.**

10/537,296

**Applicant(s)**

GUGLIELMO ET AL.

**Examiner**

Brian Guldge

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/CD)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Previous Rejections*

Applicants' arguments, filed 20 May 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 8-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Desjonquieres (US Patent 6,001,378) in view of Greff (FR Patent Publication 2,740,331) and Hino et al. (US Patent Application Publication 2003/0003072).** Applicant argues that the combination of references does not teach the composition of claims 11-15. Applicant states that claim 11 recites hydroxyproline and aspartic acid, that the instant specification recognizes that non-complexed hydroxyproline and aspartic acid are effective, and that Desjonquieres only discloses the organosilicone complex of these amino acids.

Applicant also states that claim 14 recites "active ingredients" that consist of octyl butyrate, glutamine peptides, monomethylsilanol-hydroxyproline aspartate, and benzyl nicotinate. Applicant states that the references teach the inclusion of other active ingredients that would be required for activity, and thus the references do not teach a composition with only the

instantly recited active ingredients, and there would be no reason to remove the other required active ingredients taught by the references.

Applicant further states that the combination of references fails to recognize the superior results demonstrated. The Applicant points to the declaration filed 26 October 2009, stating it demonstrates that inventive “composition B” is superior to comparative “composition A” in that the claimed composition is faster in its efficacy than the comparative composition.

The Examiner is not persuaded by these arguments. With regards to claim 11, the Applicant argues that the references do not teach the composition without the organosilicone (and with just the hydroxyproline and the aspartic acid). However, the claims do not recite that the composition does not contain the silanol, and the prior art composition does contain the two amino acids instantly recited. There is no requirement that the references meet limitations not recited by the instant claims. See MPEP 2145(VI).

For examination with regards to the prior art, the Examiner interpreted the instantly recited term “active ingredients” (instant claim 14) to be shorthand for referring to the four species of octyl butyrate, glutamine peptides, monomethylsilanol-hydroxyproline aspartate, and benzyl nicotinate. The composition recited by instant claims 14 and 15, which *comprises* the other recited ingredients, is considered to encompass compositions that contain additional bioactive agents and pharmaceutical agents other than those four instantly recited.

The reason previously put forth was that the specification discloses that the glutamine peptides (one of the four “active ingredients” recited) supports the octyl butyrate by acting as an energy supplement for cells undergoing multiplication (page 7, lines 12-15). Additionally, the declaration filed on October 26, 2009 states that the glutamine peptide provide an essential

energy source (page 7, first paragraph), and that the panthenol also acts as an energy supplement, backing up the role of the glutamine peptides (page 7, second paragraph). Thus, panthenol has the same basis for activity as the glutamine peptide (energy supplementation). As this ingredient (the panthenol) is not part of the term "active ingredient," the composition as recited by instant claim 14 contains, within its breadth, additional ingredients that are bioactive beyond the four species of octyl butyrate, glutamine peptides, monomethylsilanol-hydroxyproline aspartate, and benzyl nicotinate. Thus, the claim is not considered to exclude compositions comprising additional bioactive agents, such as those taught by the cited references.

The Examiner is also not persuaded with the asserted showing of unexpected superior results. Applicant asserts that the inventive "composition B" exhibits unexpected superior results (faster efficacy) as compared to "composition A." However, the data presented compare the results of "composition B" after 30 and 60 days, but no later, whereas the results for "composition A" are only disclosed after 90 days. There is no data presented to demonstrate the effect of each composition after the same length of time of administration. There is also no basis for the assertion presented that "composition B" is faster, as there is no comparative data from the same point in time for both compositions.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Gulledge whose telephone number is (571) 270-5756. The examiner can normally be reached on Monday-Thursday 6:00am - 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/537,296  
Art Unit: 1612

Page 6

**BMG**

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612